

Remarks

I. Status of the Application and Claims

As originally filed, the present application had a total of 18 claims. Claims 2-4, 8, 9 and 14-18 have been cancelled herein. Claims 6, 7 and 10-12 have been withdrawn as the result of a restriction requirement but are subject to possible rejoinder at allowance. Thus, the claims now pending are 1, 5 and 13.

II. The Amendments

Claim 1 was amended to specify that increased risk of a woman having ovarian cancer is measured relative to the risk of the general population. Support for this amendment may be found on page 3 of the specification, lines 1-4. Claim 1 was also amended to indicate that EDN is the protein characterized by the amino acid sequence of SEQ ID NO:1 and that test samples should have an increase in the amount of EDN of at least 20% relative to controls. Support for these amendments may be found in Figure 1 (see also page 2, lines 26-28) and page 3, lines 26-30, respectively. In addition, claim 1 was amended to indicate that test and control samples are samples of urine. Support for these amendments may be found in the examples provided in the specification.

The remaining claims were amended to maintain consistency with amended claim 1. It should be noted that the use of the descriptor “Withdrawn-currently amended” is authorized in part C of MPEP §714.

None of the amendments described above add new matter to the application and their entry is therefore respectfully requested.

The Rejections

I. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

On pages 2-3 of the Office Action, claims 1-5 and 13 are rejected under 35 U.S.C. § 112, second paragraph. The Examiner argues that the claims are indefinite because: a) the term eosinophil-derived neurotoxin is inadequate to define a protein in the absence of amino acid sequence information; b) the degree to which EDN levels must be increased in test

samples to be “significantly higher” is unclear; and c) it is unclear what basis for comparison is being used to determine that a woman is at “increased risk.”

In response, Applicants have amended claims to: a) indicate that the EDN referred to has the amino acid sequence of SEQ ID NO:1; b) indicate that EDN must be increased in test samples relative to controls by at least 20%; and c) indicate that a determination is made whether a woman is at increased risk relative to the general population. Applicants respectfully submit that these amendments address and overcome all of the Examiner’s rejections under 35 USC §112, second paragraph.

II. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

On pages 3-8 of the Office Action, claims 1-5 and 13 are rejected based upon the enablement requirement of 35 U.S.C. § 112, first paragraph. The Examiner argues that the specification only demonstrates that EDN levels in *urine* samples are indicative of the presence of ovarian cancer and that urine samples must also be used as controls.

Although Applicants do not fully agree with the Examiner, in the interest of advancing prosecution of this case, they have amended claims to recite the use of urine test samples and urine control samples. In light of these amendments, Applicants believe that the invention claimed meets the enablement requirements as set forth by the Examiner. It is therefore respectfully requested that the Examiner’s rejection of these claims be withdrawn.

Conclusion

In light of the amendments and discussion above, Applicants believe that all of the Examiner’s rejections have been overcome. It is therefore respectfully requested that these rejections be withdrawn and that the claims presently pending in the application be allowed. Early notice to this effect is earnestly solicited.

If, in the opinion of the Examiner, a phone call may help to expedite the prosecution of this application, the Examiner is invited to call Applicants' undersigned attorney at (240)864-0915.

Respectfully submitted,

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